

## **REMARKS**

By this paper, independent claim 71 has been amended.

The Applicant respectfully submits that the amendment is fully supported by the specification.

The final Office Action of December 31, 2009 has been carefully considered. It is respectfully submitted that all issues raised are traversed, being hereafter addressed with reference to the relevant headings appearing in the Detailed Action section of the Office Action.

### ***Claim Objections – 35 USC § 101***

The Examiner has rejected claims 71-78, 80-93 and 95 as being directed to non-statutory subject matter.

Independent claim 71 has been amended to recite that the base station includes "*a processing system having a processor*", and to recite "*using the processor*" in the b) ii) "*comparing...*" and b) iii) "*determining...*" steps of the method. Support for this amendment can be found in numerous parts of the original specification, for example paragraph [0140].

The Applicant respectfully submits that the amended claim 71 requires that the steps of the method to be performed on a machine and, accordingly, amended claim 71 is directed towards statutory subject matter. Claims 72-78, 80-93 and 95 are similarly directed towards statutory subject matter by virtue of their dependence upon claim 71.

### ***Claim Rejections – 35 USC § 102***

The Examiner has rejected claims 71-78, 80-93, 95 and 147 as anticipated by Hamilton et al. (US 2003/0229451).

Specifically, the Examiner has rejected claim 71, having identified portions of Hamilton et al. which allegedly show features of claim 71. However, the Applicant respectfully submits that Hamilton et al. fails to explicitly disclose all of the features of claim 71, for the reasons detailed below. Applicants also provide an overview to further clarify the distinctions between the claimed invention and the methods of Hamilton et al.

Firstly, claim 71 specifies that the method is performed using a system including at least one end station coupled to a base station *via* a communications network. In this arrangement, predetermined data are retained at the base station and not made available to the end station. As a result, this provides a mechanism by which gene expression or similar analysis can be performed whilst the security of predetermined data, such as diagnostic signatures, is maintained.

The collection of such diagnostic signatures is a time consuming, expensive and difficult process, requiring significant effort in collecting data from a number of sample subjects, diagnosing any conditions the subjects have, and then performing data mining to allow signatures to be derived. As a consequence, the signatures are extremely commercially valuable, and it is therefore desirable to ensure that these are protected from unintended exposure when providing health status analysis of subjects. Methods in the art of gene expression product testing and diagnosis typically require transport of physical samples to a laboratory to allow analysis to be performed at a location physically separated from the user, thereby maintaining the security of the diagnostic signatures.

The claimed invention addresses this issue by allowing subject data to be submitted to a base station, from an end station, via a communications network. The base station then performs a comparison of the subject data to the predetermined data, allowing results of the comparison to be determined. The results of the comparison may, for example, identify a signature to which the subject data closely relates, thereby indicating the presence, absence or degree of one or more conditions represented by the signature. Following the performance of the comparison, the results can be sent back to a user again via a communications network.

In addition, the claimed invention recites that the subject data are obtained from a single test. A user takes cells from a single biological sample obtained from a subject, such as a blood sample, and obtains the subject data therefrom. Thus, a single test can be performed at an end station, physically separated from the base station, allowing the subject data to be easily obtained. An appropriately configured end station can be deployed so that the sample can be taken from the subject, the test can be performed, and the resulting subject data transferred to the base station via a communication network, all from the subject's location. It will be appreciated that this brings substantial operational advantages.

The above process effectively allows users of the end stations to readily have access to the status of a subject without having to correlate their own predetermined data, whilst avoiding the need to collect multiple samples and without the need to physically submit collected samples for analysis. The user only needs only to obtain the subject data from the sample and then use the end station to allow the subject data to be submitted to the base station for analysis. By having the base station perform the comparison this allows the operator of the base station to restrict access to the predetermined data, thereby preventing those data from being accessed and used in an unauthorised manner by third parties. This also allows the operator to charge a fee for the provision of an indication of status of the subject. Furthermore, the user at the end station can does not need to have any specialised training, as no interpretation of the subject data is required at the base station, as this is handled at the base station.

In contrast, the process of Hamilton focuses on integrating disparate data into a coherent data set. Hamilton explains that this is useful in combining large amounts of data from different technology types into resultant data sets that can be meaningfully interpreted by skilled professionals. In paragraph 0073, Hamilton states that "biologically disparate data are data derived from different indicators of the biological status of an organism or individual" and goes on to describe examples of the different types of data that could comprise the disparate data. It follows that this disparate data would be the result of multiple different tests and not a single test, as instantly claimed.

It will be further appreciated from this that the purpose of the method and system described by Hamilton is not to allow a status of a subject to be determined, but to allow an expert user to more easily analyze large amounts of disparate data, by compiling and organising it coherently.

Although Hamilton mentions that signature profiles, indicative of the physiological status of an individual, can be established from the coherent data sets, Hamilton does not disclose establishing the signature profiles based on subject data obtained from a single test. In fact, the process of establishing a signature profile necessarily involves disparate data from multiple tests. In this regard, Hamilton describes establishing a signature profile by linking disparate data and comparing this to a reference to determine a subset of the linked data which is "most informative" in relation to a particular physiological status indicator of interest. This most informative data is merely a "filtered" version of the coherent data set, selected to simplify any subsequent analysis of the data in relation to that particular physiological status indicator.

Hamilton only mentions that these signature profiles can be for diagnostic use, but fails to describe how the signature profiles are used for diagnosis. However, Hamilton does describe scientists analyzing the data sets and signature profiles. Accordingly, it is submitted that any actual determination of the status of a subject is not performed remotely in a base station as per the claimed invention, but is performed manually by a highly trained individual, who will analyze the signature profiles to determine whether a specific condition is present. In such a process, the security of commercially sensitive data is not maintained, as it is collected, processed and provided to an end user for further analysis. A skilled person would therefore understand that the disclosure of Hamilton et al. is not particularly relevant to the claimed invention, and certainly does not anticipate claim 71.

Furthermore, it should be noted that the above mentioned comparison process of Hamilton for establishing a signature profile is not relevant to the comparison as claimed. In claim 71, the status of the subject is determined in accordance with the results of comparing subject data to predetermined data including, for each of a plurality of conditions, parameter values and an indication of the condition. On the other hand, Hamilton compares a set of coherent data with another set of baseline data corresponding to a particular condition, to establish a "most

"informative" subset of the coherent data that might be useful to a scientist in performing analysis related to that condition. A skilled person would understand that the comparison described by Hamilton has an entirely different purpose and outcome to the comparison recited in the instant claims, such that the disclosure of Hamilton is also not relevant in this regard.

Nevertheless, the Applicant submits the following comments and arguments with respect to the particular reasons for the rejection of claim 71 asserted by the Examiner.

The Examiner alleges that Hamilton discloses the features of claim 71 of an apparatus and method of determining the status of a subject using a system including an end station coupled to a base station via a communications network, with reference to the abstract, paragraphs 0013, 0018, 0022, and 0097-0109, and Figure 5. Paragraph 0018 appears to have been identified by the Examiner due to its mention of "determine the biological status of an individual", however, that this disclosure makes no mention of actually performing a status determination, and instead merely indicates different types of biological indicators that might be useful to a skilled practitioner or scientist in analyzing an individual's status. There is certainly no disclosure in Hamilton of determining the status of a subject as per the instant claims, wherein the presence, absence or degree of one or more conditions is indicated. This disclosure also has no particular relevance to the claimed system configuration.

Similarly, paragraph 0013 of Hamilton mentions a "system for establishing a signature profile indicative of the physiological status of an individual" but provides no description of the configuration of the mentioned system. As discussed above, the signature profile is not indicative of the presence, absence or degree of one or more conditions, but merely is useful in allowing a skilled practitioner to analyze the status of an individual.

Paragraph 0022 and corresponding Figure 5 show components associated with the method and system disclosed by Hamilton but similarly, provide no details of configurations, and particularly no system configuration that a skilled person would conclude correspond to an end station coupled to a base station via a communications network.

Paragraphs 0097-0109 of Hamilton mention storing data in "laboratory information management systems" ("LIMS") and proprietary databases, for example, and go on to describe the subsequent integration of data from separate sources to generate coherent data which is stored in a relational database. Although Hamilton describes examples of computer hardware and software, such as databases, and possible storage locations of the data, there is no disclosure of a specific arrangement including "*at least one end station coupled to a base station via a communications network*" as claimed. Accordingly, it is submitted that this feature of claim 71 is not anticipated by Hamilton.

The Examiner goes on to assert that Hamilton discloses the feature of claim 71 of obtaining subject data from cells from a single test including values of a plurality of parameters representative of gene expression product levels and indicative of the subject's status, with reference to paragraphs 0013-0017 and 0054-0071. Paragraphs 0013-0017 mention establishing a "signature profile indicative of the physiological status of an individual". Hamilton describes this as a "most informative" subset of a coherent data set made up of data that are linked to a unique identifier. This most informative subset of data can be found by comparing linked data to a reference. However, Hamilton clearly is directed to methods and apparatus for organising complex and disparate data into coherent data sets. The skilled person would understand that this necessarily involves taking data from a plurality of data sources, and it follows that these data would be from more than a single test.

For example, paragraph 0054 of Hamilton describes "producing a compilation of health or wellness profiles for prognostic and diagnostic use" but this clearly refers not to data that are taken from a single test, but rather to a compilation of data collected from numerous sources, which could only be results of separate tests. The following paragraphs go on to describe the different types of data that can be integrated into a coherent data set, and paragraph 0070 provides an example of compiling three different types of analysis into one data set. Clearly this requires at least three different types of tests to be performed. Thus, none of the identified disclosures of Hamilton describe obtaining subject data from only a single test. Accordingly, it is submitted that Hamilton fails to describe the use of a single test to obtain the subject data. In fact, Hamilton teaches away from use of a single test by repeatedly referring to disparate data sets.

Relying on paragraphs 0022, 0100-0109, 0113 and 0141, and Figure 5, the Examiner further asserts that Hamilton discloses the feature of receiving subject data from the end station via the communications network, which is recited in claim 71. Hamilton does not explicitly describe such a transfer of subject data from the end station to the base station. Although Hamilton makes references to different types of computer software and hardware which might be used, there is not explicit disclosure of the claimed feature. For example, paragraph 0109 describes downloading data from internet sources for integration with data from in-house repositories. However, this does not relate to a base station receiving subject data from cells from a single test, from an end station. Paragraph 0013 describes a laboratory information management system, but not the transfer of data from an end station to a base station. Paragraph 0141 refers to a user interface, but this is for a statistician to input refinements to the process of generating a coherent data set, and not for transferring subject data from an end station to a base station. Accordingly, it is submitted that this feature is also not anticipated.

The Examiner asserts that Hamilton discloses the features of claim 71 of comparing the subject data to predetermined data (i.e. reference data) and determining the status of the subject indicating the presence, absence or degree of one or more conditions, with reference to paragraphs 0017, 0072-0078, 0080-0081 and 0133. However, the comparing and determining steps of claim 71 are required to be performed in a base station, and the amendments to claim 71 now specifically require that these steps are performed using a processor in a processing system of the base station. It is respectfully submitted that this is not anticipated by the disclosure of Hamilton.

Furthermore, Hamilton fails to disclose claim 71's step of "*determining, using the processor, the status of the subject in accordance with results of the comparison*". The Examiner identifies a number of allegedly relevant disclosures in Hamilton, but these all fail to disclose the feature as instantly claimed. For example, paragraph 0072 of Hamilton mentions comparison of protein profiles from normal and diseased tissue, but the results of such a comparison are not used to determine the status of the subject. Paragraphs 0073 to 0075 describe using combined biologically disparate data, derived from different indicators of biological status, to serve as models for biological systems, which allows analysis of a coherent data set for similarities and

differences. Paragraph 0076 mentions using data derived from multiple biological indicators of physiological status to create a coherent data set, for use in validating and optimizing new targets for drug, pesticide and nutriceutical applications, whilst paragraphs 0077 and 0078 describes similar uses for new lead compounds and new drugs. Again, none of these disclosures of Hamilton involve determining the status of a particular subject, let alone the performance of the determination step in the processor of a base station.

Paragraphs 0080 and 0081 of Hamilton describe compiling health or wellness profiles for organisms, and providing profiles representative of particular diseases or other specific physiological states. Such profiles are composed of data from a single indicator of physiological status, or from any combination of such indicators. Hamilton also describes that data obtained from an individual are compared to a baseline, or reference population, to determine physiologic status. However, Hamilton does not explicitly describe any comparisons or determinations of status being performed by a processor in a base station as claimed. Hamilton in fact refers to scientists choosing the types of data most informative for a particular condition and representative of an individual's state of wellness, and on this basis, we submit that any comparison is performed by an individual and not by a processing system. Similarly, it is submitted that any status determination in accordance with the results of a comparison in the method of Hamilton would be manually performed by an individual analysing the signature profile, such as a scientist or medical professional, and not using a processor in a base station.

In the Examiner's reply to Applicant's arguments submitted in the response to the previous Office Action, the Examiner asserts that the Applicant's arguments are unpersuasive.

For example, the Examiner asserts that Hamilton discloses "obtaining subject data from cells from a single test including values of a plurality of parameters representative of gene expression product levels and indicative of the subject's status, and stage of condition", and reiterates the references to paragraphs 0013-0017, 0054-0071, 0080 and 0087. The subject matter disclosed in these identified portions of Hamilton is discussed above, but it is noted once again that none of these paragraphs of Hamilton explicitly disclose using a single test to obtain subject data including values for each of a plurality of parameters. Instead, Hamilton focuses on the use of a

number of different types of data, each of which would result from separate tests, and integrating these "disparate data" into logical coherent data sets. It is submitted that Hamilton's intended goal is the integration of disparate data into coherent data sets, and therefore the skilled person would understand that Hamilton's methods would be entirely inappropriate for using subject data from a single test, as in the case of a single test there would be no need or purpose for integrating disparate data. Accordingly, the skilled person would conclude that the disclosure of Hamilton is not relevant to claim 71.

In light of the above, the Applicant respectfully submits that amended claim 71 is both novel and non-obvious over Hamilton. Furthermore, Applicant respectfully submits that similar arguments apply to claim 147 as this claim is directed towards an apparatus configured to perform functions similar to the method steps of claim 71.

#### CONCLUSION

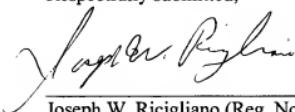
In view of the foregoing, it is respectfully submitted that the present application is believed to be in condition for allowance. Accordingly, the Applicant requests a Notice of Allowance of all the claims presently under examination

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-2283. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).**

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